IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI`I

PATRICIA SEGOVIA, *et al.* Plaintiffs, vs. BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC., Defendants.	CV. NO. 15-00519 DKW-RLP **ORDER DENYING IN PART AND GRANTING IN PART DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC.'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

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INTRODUCTION

Plaintiffs allege that Thomas Segovia died as a result of taking Eliquis, an anti-coagulant developed by Defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. Because the courts of Hawaii have not interpreted the Restatement (Second) of Torts § 402A to provide blanket immunity to all prescription drug manufacturers in the expansive manner urged by Defendants, Defendants' motion to dismiss Plaintiffs' strict liability design defect claim is DENIED. Defendants' motion is GRANTED, however, with respect to Plaintiffs' fraud allegations, which fail to provide the specificity required by Federal Rule of Civil Procedure 9(b). Plaintiffs are GRANTED LEAVE TO AMEND these assertions by **May 13, 2016.**

BACKGROUND

BMS is the holder of approved New Drug Applications ("NDA") for Eliquis, an oral anticoagulant or blood thinner. Complaint ¶ 15. In 2012, BMS and Pfizer received Food and Drug Administration ("FDA") approval to market Eliquis for multiple uses, including for atrial fibrillation. Complaint ¶¶ 21-23.

In late 2013, Segovia's medical providers discontinued the Coumadin that he had been using to address atrial fibrillation in favor of Eliquis. On December 20, 2013, Segovia suffered a severe hemorrhagic stroke from which he ultimately succumbed on July 27, 2014. Complaint ¶¶ 6, 9-10. Plaintiffs attribute Segovia's death to Eliquis. Complaint ¶¶ 41-45.

According to Plaintiffs, "Defendants negligently and fraudulently represented to the medical and healthcare community, including Decedent's prescribing doctor, the [FDA], [Segovia], and the public in general, that Eliquis had been tested and was found to be safe and effective for its indicated uses." Complaint ¶ 3. Plaintiffs contend that when Defendants designed, marketed, sold, and distributed Eliquis, they "concealed their knowledge of Eliquis' defects from [Segovia], the FDA, the public in general and the medical community, including [Segovia]'s prescribing doctor." Complaint ¶ 4.

The First Amended Complaint alleges three counts: (1) "strict liability in tort," (Count I); (2) "manufacturing and design defect," (Count II); and (3) "negligence and gross negligence" (Count III). Plaintiffs seek damages for loss of consortium, emotional distress, loss of enjoyment of life, and wrongful death, and in their prayer for relief, request compensatory and punitive damages. The instant motion seeks dismissal of all claims, except those based on Defendants' alleged failure to warn.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss for failure to state a claim upon which relief can be granted. Pursuant to *Ashcroft v. Iqbal*, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" 555 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555). Rather, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for

the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Factual allegations that only permit the court to infer "the mere possibility of misconduct" do not constitute a short and plain statement of the claim showing that the pleader is entitled to relief as required by Rule 8(a)(2). *Id*. at 679.

DISCUSSION

I. The Motion Is Denied As Moot As To The Manufacturing Defect Claims

Plaintiffs concede that they are not pursuing a manufacturing defect claim under either a strict liability or negligence theory. *See* Mem. in Opp. at 4. Although they acknowledge that Count II is entitled, "Manufacturing and Design Defect," they clarify that the manufacturing defect label was inadvertent and that their claims "are based on design defect and failure to warn theories, not on any defect particular to the Eliquis that Segovia took or that those drugs were different from the manufacturer's intended result." *Id.* Accordingly, because Plaintiffs have acknowledged that they did not intend to and do not assert a manufacturing defect claim, Defendants' motion with respect to that claim only is DENIED AS MOOT.

II. The Motion Is Denied As To Plaintiffs' Design Defect Claims

Under Hawaii law, a plaintiff's burden with respect to a claim of strict product liability "is to prove (1) a defect in the product which rendered it unreasonably

dangerous for its intended or reasonably foreseeable use; and (2) a causal connection between the defect and the plaintiff's injuries." *Tabieros v. Clark Equip. Co.*, 85 Hawai'i 336, 944 P.2d 1279, 1297 (1997). A product may be defective because it was defectively designed or carried an insufficient warning. *See Ansagay v. Dow Agrosciences LLC*, 2015 WL 9582710, at *13 (D. Haw. Dec. 29, 2015); *Torres v. N.W. Eng'g Co.*, 86 Hawai'i 383, 949 P.2d 1004, 1018 (Ct. App. 1997).

Defendants move to dismiss Plaintiffs' design defect claims "to the extent they are based on the chemical composition of Eliquis," arguing that under Restatement (Second) of Torts § 402A, comment k, prescription "medications are 'unavoidably unsafe,' in that they are incapable of being made safe for their intended and ordinary use." Motion at 11. Defendants ask the Court to adopt a blanket exemption for prescription medications from composition-based design defect claims. Neither Hawaii law, nor comment k, however, support Defendants' broad request.

Section 402A makes the seller of a product subject to liability to the user or consumer even though it has exercised all possible care in the preparation and sale of the product. Comment k, relating to "unavoidably unsafe products," provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the

> field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

"Thus, comment k provides a defense against strict liability to manufacturers of 'unavoidably unsafe' products so long as the product is (1) properly manufactured and (2) proper warnings are given." *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 167 (D. Conn. 2012).

Defendants argue that Eliquis and other prescription medications are by their nature "unavoidably unsafe." No Hawaii court, however, has so held, as a matter of

law, generally, or in the context of a motion to dismiss, specifically. The two cases relied on by Defendants, *Larsen v. Pacesetter Sys., Inc.*, 74 Haw. 1, 837 P.2d 1273 (1992), and *Forsyth v. Eli Lilly and Co.*, 1998 WL 35152135 (D. Haw. Jan. 5, 1998), certainly do not extend so far. And the out-of-jurisdiction case relied upon by Defendants, *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470 (1988), has not been adopted by Hawaii courts.[1]

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[1]The parties acknowledge that courts are split on whether comment k applies categorically to all prescription drugs or only on a case-by-case basis. The majority view does not apply comment k in the blanket manner sought by Defendants—that is, it does not categorically exempt prescription drugs from strict liability for design defect claims. *See, e.g.*, *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 170 (D. Conn. 2012) ("[T]he majority of courts that have addressed this issue have concluded that policy considerations weigh in favor of interpreting comment k as an affirmative defense that applies on a case-by-case basis."); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) ("The majority of jurisdictions that have adopted comment k apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity[.]"); *cf. Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291, at *10 (D.N.J. Jan. 7, 2013) ("Alabama deviates from the Restatement and is among the 'minority of courts [that] have interpreted comment k more broadly and provide all prescription drugs categorical immunity from strict liability for design defects.'") (quoting *Moss v. Wyeth, Inc.*, 872 F. Supp. 2d 162 (D. Conn. 2012)); *Young for Young v. Key Pharmaceuticals*, 922 P.2d 59, 64 (Wash. 1996) ("[U]nder Washington law, a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug."); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 94-95 (Utah 1991) ("[W]e are troubled by the lack of uniformity and certainty inherent in the case-by-case approach and fear the resulting disincentive for pharmaceutical manufacturers to develop new products. . . We are persuaded that all prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and the significant public policy considerations noted in *Brown*."). *See generally Weiss v. Fujisawa Pharm. Co.*, 2006 WL 3533072, at *3 n.2 & n.3 (E.D. Ky. Dec. 7, 2006) (surveying cases).

Larsen involved a medical device – the Programalith III Series pacemaker. 837 P.2d at 1278-79. Plaintiff had this pacemaker implanted, suffered complications, and sued the defendant manufacturer. *Id*. at 1278. Despite acknowledging that "comment k applies to products which, by their very nature cannot be made safe, and those upon which liability will not be imposed because the risk of harm is justified by the possible benefits of releasing such products on the market," and further acknowledging that "[c]omment k encompasses products like new or experimental drugs as to which there can be no assurance of safety," the Hawaii Supreme Court rejected the manufacturer's invocation of Section 402A, finding that the pacemaker was not an "unavoidable unsafe product." *Id*. at 1285-86. In doing so, *Larsen* employed a case-specific analysis – precisely the kind Defendants here seek to avoid – observing that because the record established that the "pacemaker was demonstrably capable of being made safe for its intended use . . . [it did not] warrant comment k exemption from strict product liability." *Id.* at 1286. The Hawaii Supreme Court therefore affirmed the lower court's denial of summary judgment sought by the manufacturer.

Forsyth v. Eli Lilly and Co., 1998 WL 35152135, at *3 (D. Haw. Jan. 5, 1998), involved a wrongful death action resulting from Prozac. Though noting that "the trend in other jurisdictions is to hold that prescription drugs are 'unavoidably

unsafe products' within the ambit of comment k," the district court acknowledged that *Hawaii* courts had not done so. 1998 WL 35152135, at *3-*4. It then denied summary judgment on "Plaintiff's strict liability design defect claim because there is a genuine issue of fact as to whether [defendant] provided an adequate warning for Prozac." *Id.* at *4. *Forsyth* is notable for its silence with respect to *Larsen* – indeed, it does not cite a single case from the Hawaii courts with respect to design defect claims or comment k – although it purports to apply Hawaii law. In short, neither *Larsen* nor *Forsyth* create a blanket rule of design defect immunity for pharmaceutical manufacturers, and the Court declines to extend comment k in a fashion that the Hawaii courts themselves have thus far declined to do.

Moreover, comment k, by its very terms, does not provide immunity to all drug makers from design defect claims. The text of the comment provides examples of high-risk drugs that, when accompanied by proper directions and warning, are neither defective nor unreasonably dangerous, and explains that the "same is true of many other drugs, vaccines, and the like . . . [and] is also true in

particular of many new or experimental drugs." But it does not speak to *all* drugs.[2] Because the clear language of the comment indicates it is to apply to only some products, the Court concludes that extending comment k protection to an entire field of products would be unwise in light of the requirements comment k specifies as prerequisite to its application, and declines to do so on the record presented. The better reasoned view is that courts should determine on a case-by-case basis whether a product is within the scope of comment k – that is, examining cost, risk, safety and policy considerations, among others, to determine whether it is an "unavoidably unsafe" product.

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[2]This plain language is underscored by the drafters' intent. The Eighth Circuit explains that the writers of the Restatement expressly rejected a proposed blanket exemption for pharmaceutical manufacturers:

> The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402A and comment k were adopted, but this proposal was defeated. 38 ALI Proc. 19, 90-98 (1961). The language of comment k suggests that only exceptional products, albeit such exceptional products are more likely to be found in the field of prescription drug products, should be excluded from the strict liability provisions. But more importantly, the example given--the vaccine for the Pasteur treatment of rabies--suggests that only special products, those with exceptional social need, fall within the gamut of comment k.

Hill v. Searle Laboratories, a Div. of Searle Pharmaceuticals, Inc., 884 F.2d 1064, 1069 (8th Cir. 1989) (footnote omitted).

Importantly, at the motion to dismiss stage, the Court cannot determine as a matter of law that Eliquis meets the criteria set forth in comment k. The Court must make a fact-intensive determination of whether Eliquis qualifies as an "unavoidably unsafe" product before comment k may be invoked in the first instance, something that cannot be done based on a review of the pleadings. Accordingly, Defendants' motion is DENIED with respect to Plaintiffs' design defect claims.

III. The Motion Is Granted As To Any Fraud-Based Allegations

Allegations of fraudulent conduct are sufficient under Fed.R.Civ.P. 9(b) only if they "identif[y] the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations." *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) (citations and quotations omitted). To sufficiently identify the circumstances that constitute fraud, a plaintiff must identify the times, dates, places, or other details of the alleged fraudulent activity. *Id.* A plaintiff must plead these evidentiary facts and must explain why the alleged conduct or statements are fraudulent:

> Averments of fraud must be accompanied by "the who, what, when, where, and how" of the misconduct charged. *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997) (internal quotation marks omitted). "[A] plaintiff must set forth more than the neutral facts necessary to identify the transaction. The plaintiff must set forth what is false or misleading about the statement,

> and why it is false." *Decker v. GlenFed, Inc. (In re GlenFed, Inc. Sec. Litig.)*, 42 F.3d 1541, 1548 (9th Cir. 1994).

Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003).

The First Amended Complaint contains numerous examples that do not meet these requirements. Plaintiffs, for instance, allege that Defendants "fraudulently represented to the medical and healthcare community . . . that Eliquis had been tested and was found to be safe and effective for its indicated uses," Complaint ¶ 3; made "[t]hese representations . . . with the intent of defrauding and deceiving Decedent, the public in general, and the medical and healthcare community . . . , all of which evinced a callous, reckless, willful, depraved indifference," Complaint ¶ 5; and "committed fraud in their conduct of the ARISTOTLE study, by concealing side effects which occurred in test users of Eliquis," Complaint ¶ 26. Plaintiffs also allege that, "[u]pon information and belief, Defendants concealed and failed to completely disclose their knowledge that Eliquis was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk." Complaint ¶ 43.

These allegations of fraud, deception, and willful misrepresentation are not pled with the particularity required by Rule 9(b). Plaintiffs do not sufficiently plead the date(s) or location(s) of each instance of the alleged fraudulent conduct, or the

person(s) making the alleged misrepresentations. *See Vess*, 317 F.3d at 1107 ("…allegations ('averments') of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b) even where "fraud is not an essential element of a claim"). Moreover, the First Amended Complaint provides little indication as to which statements are alleged to have been made fraudulently, and which negligently. When amending their complaint, Plaintiffs may not evade Rule 9(b)'s particularity requirements by alleging that misrepresentations were made *either* fraudulently or negligently. Plaintiffs' prayer for punitive damages, based on Defendants' "wanton, willful, fraudulent" conduct (Complaint, Prayer for Relief ¶ 3), likewise lacks the specificity required by Rule 9(b).

For these reasons, Defendants' motion is GRANTED with respect to Plaintiffs' allegations sounding in fraud and concomitant request for punitive damages based upon fraudulent conduct. Plaintiffs are GRANTED LEAVE TO AMEND to correct the deficiencies identified in this order by **May 13, 2016**.

CONCLUSION

Defendants' motion to dismiss is DENIED as moot with respect to Plaintiffs' manufacturing defect claims, DENIED as to Plaintiffs' design defect claims, and GRANTED as to Plaintiffs' allegations of fraudulent conduct. Plaintiffs are

GRANTED LEAVE TO AMEND to correct the deficiencies noted in this order by **May 13, 2016.**

IT IS SO ORDERED.

DATED: April 19, 2016 at Honolulu, Hawai‘i.

Derrick K. Watson
United States District Judge

Patricia Segovia, et al. v. Bristol-Myers Squibb Company and Pfizer, Inc.; Civil No. 15-00519 DKW-RLP; **ORDER DENYING IN PART AND GRANTING IN PART DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC.'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**